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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,272	08/04/2006	Mauro Ajani	622-96	7152

23117 7590 10/19/2011

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EXAMINER	
WHEELER, THURMAN MICHAEL	
ART UNIT	PAPER NUMBER
1619	
MAIL DATE	DELIVERY MODE
10/19/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,272	AJANI ET AL.	
	Examiner	Art Unit	
	THURMAN WHEELER	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *23-33,45 and 46* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *23-33,45 and 46* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/28/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 23-33, 45 and 46 are pending.

2. Claims 23 and 31 have been amended.

3. Herein, claims 23-33, 45 and 46 are for further prosecution.

4. Any objection not reiterated in this Action is withdrawn.

5. The following office action contains NEW GROUNDS of Rejection.

Rejections Withdrawn

6. The rejection of claims 23-33, 45 and 46 under 35 U.S.C. 103(a) as being unpatentable over Anisson et al (WO9513801, IDS) and in view of Bird et al (WO0202102, IDS) and Villa et al (EP 1183014, IDS) is withdrawn in view of applicant's amendments and the NEW GROUNDS of Rejection.

NEW GROUNDS of Rejection

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
2. Ascertaining differences between the prior art and claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 23-33, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Salimath et al (US 20030185917; Pub. Date: Oct. 2, 2003) in view of Thibault et al (USP 5099009, Pub. Date: Mar. 24, 1992) and Villa et al (EP 1183014, Pub. Date: March 06, 2002, cited in IDS of 8/05/2010).

9. Applicant's claimed invention is directed towards an oral pharmaceutical or dietary composition comprising an active ingredient and a complex sugar and/or dietary fibre, said active ingredient consisting of at least one short-chain fatty acid or salt, ester and/or amide thereof, in which the complex sugar and/or dietary fibre is selected from inulin, pectin, dextrin, maltodextrin or derivatives thereof and with one or more pharmacologically acceptable excipients, said composition comprising (a) a matrix consisting of lipophilic compounds with a melting point lower than 90°C and optionally amphiphilic compounds in which the active ingredient are at least partially

incorporated, (b) an amphiphilic matrix; and (c) an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed.

10. Salimath teaches a synergistic pharmaceutical composition comprising butyric acid, wheat fibre bran and guar gum (Abstract; [0014]; see entire document), wherein butyric acid 1-1000 mg/kg body weight and an insoluble wheat fibre bran 1-5% ([0016]; see examples 1-4).

Salimath teaches dietary fibre in the diet has many beneficial effects including slowing macromolecular digestion, slow release and absorption of glucose etc. Salimath teaches butyric acid is recognized for its role at the molecular level [0004]. Salimath teaches that the dietary fibres are fermented by microbes in the colon to short chain fatty acids, e.g. butyric acid-a four carbon fatty acid [0003].

Further, Salimath teaches dietary fibre acts as a reservoir of butyric acid and has supplementary beneficial effect [0005]. Furthermore, Salimath teaches the insoluble fibre wheat bran of said composition gets fermented all along the intestinal tract and acts a reservoir of butyric acid [0023].

Salimath teaches the sustained release of butyric acid of said composition is effective in the treatment of diabetic nephropathy [0022].

Thibault teaches a composition comprising pectins derived from wheat bran that are used as alimentary fibers. Further, Thibault teaches that this composition can take the form of small-sized aggregates such as tablets, granules and the like, or else a pulverulent form (col.1, lns.10-12; col.2, lns.36-57; col.3, lns.49-56; see entire document).

However, Salimath does not explicitly embody formulating a composition comprising butyric acid and wheat bran in a controlled release composition comprising a matrix consisting of the lipophilic compounds, an amphiphilic matrix and an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed.

Villa teaches a controlled release and taste masking oral pharmaceutical composition containing an active ingredient, comprising (a) matrix consisting of the lipophilic compounds with a melting point lower than 90°C and optionally amphiphilc compounds in which the active ingredient are at least partially incorporated (b) an amphiphilic matrix; and (c) an outer hydrophilic matrix in which the lipophilic matrix and the amphiphilic matrix are dispersed [0018]. Furthermore, Villa teaches that this three component matrix structure can be used for the control of the dissolution of an active ingredient to modulate the dissolution of the active ingredient in aqueous

and/or biological fluids, thereby controlling the release kinetics in the gastrointestinal tract [0001]. Villa teaches the compositions can further contain conventional excipients, i.e. chitosan and acrylic polymers [0034]. Villa teaches compositions in the form of tablets, capsules and minitablets (claim 10).

It would have been obvious to one skilled in the art at the time of the invention to modify the dietary pharmaceutical as taught by Salimath to provide a controlled release and taste-masking delivery system comprising a three component matrix whereby the active ingredient (i.e. SCFA) is released in the gastrointestinal tract as taught by Villa. One skilled in the art would have been motivated to do so because Salimath teaches that butyric acid is important on the molecular level, wherein the sustained release of butyric acid is effective in the treatment of diabetic nephropathy. Moreover, Salimath teaches a synergistic pharmaceutical composition comprising butyric acid and wheat fibre bran.

One skilled in the art would have recognized that wheat bran was a source of pectin and that a modified product comprising soluble fibres, e.g. pectin, could be provided in accordance with the teaching of Thibault. Furthermore, one skilled in the art at the time of the invention would have had a reasonable expectation of success to provide a dietary

composition comprising varied amounts of pectin in a controlled release composition in accordance with routine experimentation by following the teachings of Salimath, Thibault and Villa, as a whole.

Accordingly, the claimed invention of instant claims 23-33, 45 and 46 were prima facie obvious to one skilled in the art at the time of the invention was made especially in the absence of evidence to the contrary.

Response to Arguments

11. Applicant's arguments and Affidavit by Luigi filed on July 08, 2011 with respect to claims 23-33, 45 and 46 have been considered but are moot in view of the new ground(s) of rejection. It is noted, however, that Salimath teaches a synergistic pharmaceutical composition comprising butyric acid and wheat bran. The butyric acid is not covalently bonded to a carrier; the butyric acid (SCFA) is a single molecule, without any link with a complex sugar and/or dietary fibre in accordance with applicant’s claimed invention.

Conclusion

12. No claims are allowed.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on 9:00 a.m.-5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached (571)272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

T.W.

/Anne M. Gussow/

Primary Examiner, Art Unit 1643